

REMARKS

The pending Office Action addresses and rejects claims 38-40, 42-57, and 68-73.

Amendments to the Claims

Applicants amend claim 47 to remove a term for which proper antecedent basis was not provided, and in particular to replace “any of the at least one portion” with “the filament.” No new matter is added.

Rejections Pursuant to 35 U.S.C. §102(b)

(1) Independent Claims 38, 47, 49, 52, 57, and 72

Claims 38-40, 42-45, 52, 54, 57, and 72 continue to be rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,702,397 of Goble et al. (“Goble”), and claims 47, 49, 51, 53, and 56 continue to be rejected pursuant to 35 U.S.C. §103(a) as being obvious over Goble. Applicants respectfully disagree.

(a) Independent Claim 47

Independent claim 47 recites a device for anchoring a filament to tissue or bone having an anchor member with first and second components adapted to hold a filament therebetween by interference fit. Claim 47 further requires that the filament have a breaking strength that is greater than a threshold force, and that the filament be substantially non-movable in response to a tensional force less than a threshold force applied to any of the at least one portion, and the filament be longitudinally movable in response to a tensional force greater than the threshold force applied to any of the at least one portion. In other words, claim 47 requires that the suture slides before it breaks when a force greater than the threshold force is applied thereto. Goble does not teach or even suggest a suture anchor that would allow any suture, regardless of the properties of the suture, to slide before it breaks.

Goble discloses a suture anchor that uses a *mechanical interlock* to retain a suture, as shown in Figures 13, 16, and 17. The mechanical interlock relies on corresponding surface features which positively engage one another to hold the components together. The positive engagement between

the surface features will prevent movement of any suture disposed therebetween altogether. Thus, a suture trapped between Goble's mechanically interlocked components will break before it moves. In fact, the use of a mechanical interlock may cause the suture to break during normal use as the mechanical interlock between the ridges could potentially damage the suture.

Goble actually makes it clear that the suture anchor is configured to permanently *lock* the suture therebetween, and thus prevent any sliding. In the Summary of the Invention section, Goble generally describes the various embodiments of the invention as including "a movable member to lock against those sutures or shafts within the anchor, prohibiting their return travel back through the anchor from proximal to distal ends so as to maintain a tension and length applied through the sutures or shafts." Col. 2, lines 17-21. Goble further explains that, in one embodiment,

with a tension applied to the suture through the device distal end, the spherical ball will be pulled by that suture or sutures towards the cavity concave section, that is preferably serrated, pressing the suture or sutures against the cavity wall serrations and/or concave section, thereby prohibiting travel of the suture back through the device from proximal to distal ends. A tension applied to the suture through the bone anchor device of the invention will thereby *permanently lock* the suture within the device.

Col. 3, lines 20-29. Throughout the remainder of the specification, Goble continues to explain that a suture is locked in place within the device. Accordingly, Goble makes it clear that the device is configured to lock a suture and prevent any sliding from occurring. Claim 47 therefore distinguishes over Goble and represents allowable subject matter. Claim 47 also distinguishes over Goble for reasons discussed in section (b) below.

(b) Independent Claims 38, 49, 52, 57, 68, and 72

Independent claims 38, 47, 49, 52, 57, 68, and 72 each require a suture anchor that is adapted to hold a suture by an *interference* or *compression* fit. In the Advisory Action dated June 28, 2005, the Examiner submits that the claim language does not positively recite structure that precludes Goble's suture anchor. Applicants respectfully disagree.

As previously explained, and as evidenced by the §1.132 Declaration of Mehmet Sengun previously submitted, an interference or compression fit is a specific type of fit that is different than a mechanical interlock. These two distinct types of fits require distinct structures, and any person

having ordinary skill in the art appreciates and understands these differences. In particular, an interference or compression fit requires a structure that relies *solely* on an amount of normal compression forces created between two surfaces to retain a suture therebetween. A mechanical interlock, on the other hand, requires a structure that utilizes corresponding surface features which positively engage one another to hold the components together. While a suture may become compressed between two components that mate using a mechanical interlock, the suture is not held by an *interference fit* or a *compression fit*, as the structure is entirely different. Accordingly, because claims 38, 47, 49, 52, 57, 68, and 72 recite an interference fit or a compression fit that holds a suture, these claims positively recite structure precluded by Globe.

Accordingly, claims 38, 47, 49, 52, 57, 68, and 72 therefore distinguish over Goble and represent allowable subject matter. Dependent claims 39-40, 42-48, 50-51, 53-56, and 69-71 are allowable at least because they depend from an allowable base claim.

(2) Independent Claims 68 and 73

The Examiner also rejects claims 50, 55, 68-71, and 73, all of which require a frangible portion, pursuant to 35 U.S.C. §103(a) as being obvious over Goble in view of Reissue Patent No. 36,289 of Le et al. ("Le"). Applicants respectfully disagree.

As shown in Figures 16 and 17, Goble discloses a tool (70) that is used to rotate and drive a set screw (60) into a plug (50) that is disposed within the anchor (40). The tool (70) includes several short posts (74) formed on the distal end thereof and adapted to be disposed within corresponding holes 64 formed in the set screw (60). The Examiner argues that it would have been obvious in view of Le to modify the tool (70) to be frangibly coupled to the plug (60) to facilitate removal of the tool. This is incorrect for several reasons.

(a) The Examiner Has Failed To Establish A Prima Facie Case Of Obviousness

The Examiner has failed to establish a prima facie case of obviousness. It would not have been obvious to modify the anchor of Goble to include a frangible connection as taught by Le because such a modification would interfere with the intended function of the Goble anchor. The anchor disclosed in Figures 16 and 17 is specifically designed to allow the suture to be released. Thus, when the anchor is first implanted, the tool is used to thread the set screw (60) into the plug

(50) to lock the sutures in place. When release or adjustment of the suture is later desired, for example to adjust the tension of the ligament, the tool can again be inserted through the anchor (40) to rotate the set screw (60) in an opposite direction to release the suture from the anchor. (See Col. 4, line 60 to Col. 5, line 7, and Col. 10 lines 51-59.) The use of a frangible connection to mate the tool to the set screw, as suggested by the Examiner, would prevent the tool from being used as required by Goble to adjust the tension or release the suture. Once the tool is frangibly removed from the set screw the tool cannot be used again to rotate the set screw. Accordingly, the use of a frangible connection is specifically contrary to the teachings of Goble and would render the device useless for its intended purpose.

(b) The Examiner Has Failed To Identify A Motivation To Combine The References, And Rather Is Improperly Relying On Hindsight

The Examiner fails to apply the legal requirement that the prior art be shown to provide sufficient motivation to one of ordinary skill in the art to combine the references. In combining references to support an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The teaching or motivation must come from the references, and it cannot be derived from Applicant's teachings.

There is no motivation to modify the anchor of Goble to include a frangible connection as taught by Le. Le utilizes a frangible connection to allow the tool to be used to engage and guide the wedge member onto the anchor. This is not necessary with the Goble device because the set screw (60) is pre-disposed within the anchor. The use of any type of frangible connection with the Goble device would therefore be disadvantageous. A frangibly attached rod would render the device more difficult to operate, as the rod would have to be separated from the set screw. Goble already provides a simple and effective method for inserting the set screw into the plug of the bone anchor.

In a telephone call with the Examiner on May 26, 2005, the Examiner also argued that Goble inherently discloses a frangible connection between the tool and the set screw. For the same reasons stated above, Applicants respectfully disagree. The Goble anchor is specifically designed to allow for release or adjustment of the suture, as may be necessary over time. The tool therefore cannot be inherently frangible as this is specifically contrary to the teachings of Goble. The tool is further not

inherently frangible as it does not include a reduced diameter region that would allow the tool to break apart from the set screw. The entire shaft of the tool has a substantially constant, rather large diameter, and the distal end of the tool has an increased diameter. No portion of the tool includes a reduced diameter region that would allow for breakage to occur. Even if breakage could occur, this would be undesirable as the distal end of the tool would be left floating in the patient's body since it is not attached to the set screw.

The Examiner's reliance on an allegedly inherent disclosure by Goble is also misplaced. "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269, 20 U.S.P.Q.2D (BNA) at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981)). The frangible connection that is missing from the Goble reference is clearly not necessarily present, and it certainly would not be so recognized by persons of ordinary skill. In fact, Goble cannot be relied on to establish inherency because Goble specifically requires that driver tool be separate from the set screw to allow for later adjustment. The Examiner has not provided any basis in fact or technical reasoning to support a determination that a frangible connection on the tool necessarily flows from the teachings of Goble.

In conclusion, the Examiner's obviousness rejection can only be the product of impermissible hindsight. An Examiner may only establish a prima facie case of obviousness when "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). In asserting that the prior art "suggested" the claimed subject matter, however, an Examiner must realize that "the mere fact that the prior art may be modified in the manner proposed by the Examiner neither makes the modification prima facie obvious nor obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). "[A] rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Werner Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Moreover, the Examiner may not "use

the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *Id.* The Federal Circuit has further stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.*

Applicant was motivated by problems discovered, and which were not recognized by Goble and Le, to develop a unique configuration for a device for anchoring tissue to bone. The Examiner's picking and choosing of features out of context from two different references in an attempt to construct a prima facie obviousness rejection boils down to an impermissible hindsight reconstruction of Applicant's invention. Applicant's claimed invention is patentable over the combination of Goble and Le.

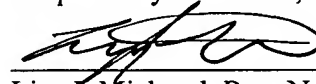
Accordingly, claims 50, 55, 68-71, and 73 distinguish over Goble and Le and therefore represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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